State of California—Health and Human Services Agency
California Department of Public Health

TOMÁS J. ARAGÓN, M.D., Dr.P.H
Director and State Public Health Officer

GAVIN NEWSOM
Governor

November 10, 2021

Adam Rosendorff, MD
CLIA Laboratory Director
CDPH Branch Laboratory
28454 Livingston Ave
Valencia, CA 91355

Timothy Bow
Emergency Procurement Officer, Owner Representative
California Department of Public Health
850 Marina Bay Parkway, Bldg. P
Richmond, CA 94804

STATE: CPH889339
CLIA: 05D2197416

RE: PUBLIC HEALTH LABORATORY STATE INSPECTION

Routine Inspection

NOTICE OF ACCEPTANCE OF CORRECTION OF DEFICIENCIES

Dear Dr. Rosendorff,

On October 21, 2021, the California Department of Public Health (Department) notified your laboratory of its intent to impose the alternative sanctions of a directed plan of correction and onsite monitoring as a result of its determination that your laboratory was not in compliance with the requirements specified in the Health and Safety Code (HSC) section 101160 and/or California Code of Regulations (CCR), title 17, sections 1078 and 1083.

After extensive review and careful analysis of evidence and documentation submitted by your laboratory, the Department hereby notifies you of the withdrawal of its intent to impose the above-described alternative sanctions.

The findings are as follows:

1. The Department conducted a routine inspection of your laboratory on December 8, December 9, and December 16, 2020. The routine inspection concluded on February 17, 2021.
2. On February 19, 2021, the Department notified you of its determination that the laboratory was **not** in compliance with the requirements specified in HSC section 101160 and/or California Code of Regulations (CCR), title 17, sections 1078 and 1083.
3. In response, the Department received four submisions from your laboratory on March 1, March 8, March 11, and March 30, 2021.
4. On May 17, 2021, the Department notified you that the four previous submissions failed to remove all condition level deficiencies.
5. On May 24, 2021, the Department received a written submission from your laboratory in response to our May 17, 2021, letter.
6. On June 8, 2021, the Department notified you that the May 24, 2021, submission failed to remove the remaining condition level deficiency and that this notification would be the Department's final request for information.
7. The Department received email communications from your laboratory June 18, 2021 and July 3, 2021, and another submission on August 20, 2021.
8. After careful review of all submissions, the Department determined that your laboratory failed to correct a remaining condition level deficiency (**D5400 – 42 C.F.R. section 493.1250; Condition: Analytic Systems**).
9. On October 21, 2021, the Department sent your laboratory a "Notice of Intent to Impose Sanctions" based on the failure to correct the condition level deficiency.
10. The Department received another submission from your laboratory on October 27, 2021, and it referred to documents your laboratory submitted on September 10, 2021, to another regulatory entity but did not submit to the Department.
11. On October 28, 2021, the Department directed your laboratory to submit the same documents to supplement your October 27, 2021, submission.
12. The Department received a submission from your laboratory on November 2, 2021, and conducted an onsite visit of the laboratory on November 10, 2021.

Upon review of all submissions received by the Department subsequent to the "Notice of Intent to Impose Sanctions," the Department has found that the corrections and evidence submitted by your laboratory are acceptable. Because all defiencies previously cited by the Department have been found to be corrected, no further action with respect to the findings of the routine inspection of your laboratory is required.

Please note that the inspection takes an overview of the laboratory through random sampling. By its nature, an inspection may not find every instance of non-compliance that may have occurred in the laboratory. It remains the responsibility of the laboratory

and its director to ensure that the laboratory is at all times following all state laws and regulations related to clinical laboratory requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur. Compliance with these laws and regulations is your responsibility as a licensee in retaining the rights and privileges granted by the Public Health Laboratory License.

We appreciate the time, cooperation, and effort that was given to address the findings of the Department's routine site inspection.

Sincerely,

Elsa Eleco
Section Chief, On-Site Licensing

cc: Catherine C. Tolentino
Examiner II

Robert J. Thomas
Branch Chief, Laboratory Field Services

LeeAnn Dennewitz
SVP, Strategic Partnerships & Alliances, PerkinElmer